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# HIGH CRIMES, NOT MISDEMEANORS: DETERRING THE PRODUCTION OF UNSAFE FOOD

*Rena Steinzor*<sup>†</sup>

“Enron is indicative of nothing . . . There’s always people who do something they shouldn’t and you’ll never be able to legislate against it. This stuff happens.”

Alan Greenberg, Chairman, Executive Committee, Bear Stearns<sup>1</sup>

“FDA regulates food manufacturers’ safety practices by relying on companies’ self-interest in producing safe products, and by working with the industry to improve production practices.”

Geoffrey Becker, Congressional Research Service<sup>2</sup>

The FDA needs the ability to criminally prosecute quickly and effectively when needed. If someone is convicted of a felony in the criminal justice system, they go to prison and are not allowed to vote. But, if you poison Americans via their food supply what are the consequences? You pay a fine and keep producing? Is this right? Is this what we as Americans want?

Peter Hurley, police officer, Portland, Oregon and father of surviving salmonella-poisoned child.<sup>3</sup>

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<sup>1</sup> Steven Pearlstein, *Debating the Enron Effect: Business World Divided on Problem and Solutions*, WASH. POST, Feb. 17, 2002, at A1.

<sup>2</sup> GEOFFREY S. BECKER, CONG. RESEARCH SERV., THE FEDERAL FOOD SAFETY SYSTEM: A PRIMER 2 (2009), available at <http://www.nationalaglawcenter.org/assets/crs/RS22600.pdf> [hereinafter CRS PRIMER].

<sup>3</sup> Mr. Hurley is the father of Lauren, 5, Jacob, 3, and Alyssa, 8 months. Jacob was sickened by Austin peanut butter crackers in January 2009, but survived.

## OVERVIEW

In the fall of 2008, Minnesota public health officials became alarmed by an unusually high number of illnesses and deaths caused by salmonella poisoning. Using the tedious and time-consuming “traceback process,” which involves interviewing victims in detail about their eating habits to discover common foods,<sup>4</sup> graduate students employed by the state part-time and jokingly referred to as the “Diarrhea Squad,” eventually determined that the victims had all consumed peanut products that were supplied to schools, nursing homes, and other institutions by the Peanut Corporation of America (“PCA”).

PCA had two processing plants: one in Blakely, Georgia and a second in Plainview, Texas. While the mainstream media demanded details about the outbreak, which ultimately killed nine and sickened 660, federal, state, and congressional investigators swarmed to PCA’s facilities in Blakely, Georgia and Plainview, Texas.<sup>5</sup> Within weeks, both plants closed and the company declared bankruptcy.<sup>6</sup> Media accounts and congressional oversight hearings revealed several shocking facts about the facility and the absence of any effective government oversight of its operations:

- Plant operators knowingly shipped peanut products to their customers after these materials had tested positive for salmonella. In an effort to justify their activities, the plant operators continued to retest these products until they achieved a negative result.<sup>7</sup>

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*The Salmonella Outbreak: The Continued Failure to Protect the Food Supply: Hearings Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy and Commerce*, 111th Cong. 5 (2009) (testimony of Peter K. Hurley), available at [http://energycommerce.house.gov/Press\\_111/20090211/testimony\\_hurley.pdf](http://energycommerce.house.gov/Press_111/20090211/testimony_hurley.pdf) [hereinafter *The Salmonella Hearings*].

<sup>4</sup> For a description of this methodology, see *The Salmonella Hearings*, *supra* note 3, at 2-5 (testimony of Stephen F. Sundlof, Director, Center for Food Safety and Applied Nutrition, Food & Drug Admin.), available at [http://energycommerce.house.gov/Press\\_111/20090211/testimony\\_sundlof.pdf](http://energycommerce.house.gov/Press_111/20090211/testimony_sundlof.pdf) [hereinafter Sundlof Testimony].

<sup>5</sup> Karla Cook, *Peanut Recall’s Ripples Feel Like a Tidal Wave for Some Companies*, N.Y. TIMES, Feb. 26, 2009, at B6.

<sup>6</sup> Andrew Martin, *Troubled Peanut Company Files for Bankruptcy Protection*, N.Y. TIMES, Feb. 14, 2009, at B2.

<sup>7</sup> The most notorious e-mail exchange, between PCA president Stewart Parnell and Joe Valenza, the Vice President for Finance and Administration of the King Nut Companies, reads:

- The Texas plant operated unlicensed and had not been inspected by state officials for nearly four years.<sup>8</sup> Testing at the Texas plant in February 2009 indicated possible salmonella contamination of the facility, former employees told the *New York Times* that the facility was “disgusting,” and the company ultimately agreed to close the facility voluntarily.<sup>9</sup>
- The Georgia plant was awash in outright safety violations and unwise management practices, such as a leaking roof, mold growing on ceilings and walls, rodent infestation, filthy nut processing receptacles, and feathers and feces in its air filtration system.<sup>10</sup>
- Under an agreement with the Food and Drug Administration (FDA), Georgia state inspectors visited the PCA plant nine times in 2006-2008, but state officials took no effective action to terminate any of these conditions. Inspectors tested processed peanuts at the facility for salmonella only once, despite widespread news reports at the time regarding a comparable outbreak at a ConAgra plant seventy-five miles away in Sylvester, Georgia; the test came up negative and the plant continued to operate.<sup>11</sup>

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Parnell to Valenza: “Joe, I’m sure it’s something we did.”

Valenza to Parnell: “Now my heart is really in my throat. I think I’m going to church tonight.”

This exchange was quoted by Representative Bart Stupak. *The Salmonella Outbreak—The Role of Industry in Protecting the Nation’s Food Supply: Hearing Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy & Commerce*, 111th Cong. 2 (2009), available at [http://energycommerce.house.gov/Press\\_111/20090319/stupak\\_open.pdf](http://energycommerce.house.gov/Press_111/20090319/stupak_open.pdf) [hereinafter *Stupak Statement*] (opening statement of Rep. Bart Stupak, Chairman, Subcomm. on Oversight & Investigations of the H. Comm. on Energy & Commerce); see also Gardiner Harris, *Salmonella Was Found at Peanut Plant Before*, N.Y. TIMES, Jan. 29, 2009, at A15 (noting that PCA shipped foods that retested negative for salmonella twelve times in 2007 and 2008).

<sup>8</sup> Gardiner Harris, *After Tests, Peanut Plant in Texas Is Closed*, N.Y. TIMES, Feb. 11, 2009, at A14.

<sup>9</sup> *Id.*

<sup>10</sup> *Stupak Statement*, *supra* note 7, at 3 (requesting that the vivid descriptions of these conditions, and photographs that document them, be entered into the congressional record); see also Michael Moss, *Peanut Case Shows Holes in Food Safety Net*, N.Y. TIMES, Feb. 9, 2009, at A1.

<sup>11</sup> The ConAgra outbreak occurred in 2007 and sickened more than 600 people, but no one died. ConAgra’s total business dropped twenty percent during the seven months the peanut butter was off the shelves. Kim Severson, *Who’s Sticking with Us?*, N.Y. TIMES, Feb. 4, 2009, at D1; see also Moss, *supra* note 10.

- Georgia employs sixty field inspectors to cover 16,000 facilities, ranging from processing plants to food storage warehouses.<sup>12</sup>
- The Georgia plant had received a “superior” rating from a private audit firm, American Institute of Baking International (AIB), barely a year before the outbreak, although a second auditing team hired by its customer Nestlé Inc. had turned in such a damning report that Nestlé stopping buying products from PCA.<sup>13</sup>
- When called to testify before Congress, Stewart Parnell, PCA’s chief executive officer, invoked his Fifth Amendment right not to incriminate himself.<sup>14</sup> The company, and not Mr. Parnell, ultimately became the target of a criminal investigation.<sup>15</sup>
- The outbreak resulted in the recall of some 2100 products containing PCA peanuts. It cost the peanut industry \$1 billion and uncounted hundreds of millions more were spent by its customers, large and small manufacturers of everything from cereal to health store granola bars.<sup>16</sup>

Outbreaks of food-borne illness cause 5,000 deaths, hospitalize 325,000 Americans, and make 76 million people sick annually, according to a 1999 estimate by the Centers for Disease Control.<sup>17</sup> The Government Accountability Office (GAO) puts these numbers considerably higher, estimating in 1996 that food-borne illness kills 9,100 people and makes 81 million people sick.<sup>18</sup>

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<sup>12</sup> *The Salmonella Hearings*, *supra* note 3, at 1 (testimony of Oscar S. Garrison, Assistant Commissioner, Consumer Protection Division, Georgia Department of Agriculture), available at [http://energycommerce.house.gov/Press\\_111/20090211/testimony\\_garrison.pdf](http://energycommerce.house.gov/Press_111/20090211/testimony_garrison.pdf).

<sup>13</sup> Andrew Martin, *Peanut Plant Says Audits Declared It in Top Shape*, N.Y. TIMES, Feb. 5, 2009, at B10; Lyndsey Layton, *Nestlé’s Inspectors Saw Rat Droppings, Rejected Peanuts*, WASH. POST, Mar. 20, 2009, at A2.

<sup>14</sup> Gardiner Harris, *Peanut Foods Shipped Before Testing Came In*, N.Y. TIMES, Feb. 12, 2009, at A24.

<sup>15</sup> See Rob Stein, *FDA Investigating Peanut Company Behind Recall: Firm Could Face Criminal Charges*, WASH. POST, Jan. 31, 2009, at A2. Corporations targeted for criminal prosecution are not jailed, of course, but are liable for fines.

<sup>16</sup> Emily Fredrix, *Salmonella Recall Could Cost Peanut Producers \$1 Billion*, INS. J., Mar. 12, 2009, available at <http://www.insurancejournal.com/news/national/2009/03/12/98635.htm>.

<sup>17</sup> These widely cited figures are from a 1999 report by the Centers for Disease Control. See Paul S. Mead et al., *Food-Related Illness and Death in the United States*, 5 EMERGING INFECTIOUS DISEASES 607, 607 (1999).

<sup>18</sup> RES., CMTY., & ECON. DEV. DIV., U.S. GEN. ACCOUNTING REP. NO.

The 2009 peanut scandal propelled Congress to put food safety to the top of its legislative agenda; the House of Representatives passed legislation in July 2009, and Senate leaders have pledged to follow suit.<sup>19</sup> The bills would dramatically expand the FDA's regulatory authority and increase agency funding for the implementation of these stringent new authorities. Both pieces of legislation strengthen the penalties available for violations of their new provisions. However, in one of the most perplexing instances of legislative under-reaction to a public health crisis in recent memory, the Senate bill does not strengthen the existing criminal penalties available for such violations. Under existing law as left intact by the Senate bill, even the egregious conduct of PCA owner Stewart Parnell would be punishable as a misdemeanor, with a maximum penalty of not more than one year in jail and a \$1,000 fine.<sup>20</sup> In contrast, the legislation passed by the House would raise this penalty to a felony for comparable future acts, punishable by up to ten years in jail<sup>21</sup> and a fine determined under the provisions of Title 18 of the U.S. Code. Those provisions cap individual assessments at \$250,000 and corporate assessments at \$500,000 unless the pecuniary benefit to the defendant is greater than those amounts, in which case the person can be compelled to pay twice the gross amount of the gain.<sup>22</sup>

At a time when regulatory agencies are being asked to do much more with less, why have Senate lawmakers neglected the relatively inexpensive and effective approach of authorizing criminal liability for the worst violators? What concerns, legitimate and bogus, block the return to deterrence-based enforcement of stringent, proscriptive regulation? This article makes a start on answering those questions, which have implications beyond food safety. I contend that Senate legislators' decision to leave blatant violations of food safety law punishable as a mere misdemeanor reflects a counterproductive ambivalence regarding the prosecution of white collar crime. During an era when victims defrauded by the largest Wall Street Ponzi scheme in history were marching in the streets to ensure that Bernard Madoff

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GAO/RCED-96-96, FOOD SAFETY: INFORMATION ON FOODBORNE ILLNESSES 4 (1996), available at <http://www.gao.gov/archive/1996/rc96096.pdf>.

<sup>19</sup> Gardiner Harris, *Bipartisan Group Demands Overhaul on Food Safety*, N.Y. TIMES, Mar. 12, 2009, at A20.

<sup>20</sup> See Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 333(a)(1) (2006). Repeat violators are liable for up to three years in jail and a \$10,000 fine. § 333(a)(2).

<sup>21</sup> Food Safety Enhancement Act, H.R. 2749, 111th Cong. § 134 (2009).

<sup>22</sup> 18 U.S.C. § 3571 (2006).

would never emerge from jail, this attitude is as baffling as it is remote from public sentiment.<sup>23</sup>

The article opens with a brief diagnosis of why the existing food safety system is dysfunctional. It explores the fundamental theories behind deterrence-based enforcement and rebuts the arguments advanced by conservative economists against those theories in a white collar context. It concludes with a proposal for enhancing the penalty provisions in pending legislation while providing a defense for corporate actors who exercise due diligence in complying with strengthened regulations.

Congress should embrace stringent criminal liability provisions because misconduct in certain areas of food production has mortal consequences for consumers. Globalization of the economy, which has produced a surging market for imported foods, means that federal and state regulators will never succeed if their sole focus is inspecting their way out of trouble. Rather, Congress must create harshly negative incentives for larger food processors through the imposition of strict criminal liability for both deliberate and negligent malfeasance within the supply chain. Expansive criminal liability for individuals and corporations should become a weapon of first resort because small numbers of well-publicized prosecutions have tremendous potential to create and maintain those incentives.

Although problems with the Department of Agriculture's food safety programs, which govern the production of meat, poultry, and eggs, are very important, and have direct implications for the FDA's failures, they are beyond the scope of this discussion. The details of the FDA's regulatory programs, now and under the pending legislation, are also given short shrift in order to keep a tight focus on the utility of criminal prosecution in situations similar to the peanut scandal described in the opening pages of this piece.

## I. REGULATORY DYSFUNCTION AT THE FDA

The U.S. population spends "more than \$1 trillion on food each year, nearly half of it in restaurants, schools, and other places outside the home."<sup>24</sup> An estimated fifteen percent of the food Americans eat

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<sup>23</sup> See Kevin McCoy, *Victims' Anger Shifts Past Madoff: Criticism Turns to Role SEC and Others May Have Played and How They'll Be Repaid*, USA TODAY, June 30, 2009, at 1B. Bernard Madoff is a former Wall Street trader and investor who ran what is estimated to be the largest Ponzi scheme in history, ultimately defrauding his customers of billions of dollars.

<sup>24</sup> CRS PRIMER, *supra* note 2, at 1; see also ECON. RESEARCH SERV., U.S. DEP'T OF AGRIC., FOOD SECTOR 335 (2009), <http://www.ers.usda.gov/Browse/FoodSector/> (explaining that roughly two-thirds of this amount pays for domestically

is imported, much of it from countries without any effective food safety regulation.<sup>25</sup> The FDA is responsible for regulating eighty percent of that food;<sup>26</sup> everything other than meat and poultry fall within its jurisdiction, although other agencies share responsibility for eggs, fish, and pesticide residues on produce.<sup>27</sup> The FDA has jurisdiction over more than 44,000 U.S. food manufacturers, as well as over 100,000 additional registered food facilities including warehouses and grain elevators.<sup>28</sup> Some 200,000 foreign food facilities have filed FDA registrations, but given the highly decentralized structure of food production and processing in developing countries like China, it is difficult to imagine that this figure comes close to an accurate estimate of the number of places where imported food originates.<sup>29</sup>

As is the case with other health and safety agencies, FDA food safety programs are undermined by three severe problems: (1) acute funding shortages, (2) outdated statutory authority, and (3) the enormous challenges posed by imported food. These crippling conditions are well-documented in a series of reports by the National Academies' Institute of Medicine,<sup>30</sup> the FDA's own independent science advisory board,<sup>31</sup> the Congressional Research Service (CRS),<sup>32</sup> the Government

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produced farm foods; imports and seafood account for the remainder).

<sup>25</sup> GEOFFREY S. BECKER, CONG. RESEARCH SERV., U.S. FOOD AND AGRICULTURAL IMPORTS: SAFEGUARDS AND SELECTED ISSUES 3 (Apr. 2009), *available at* <http://www.nationalaglawcenter.org/assets/crs/RL34198.pdf> [hereinafter CRS SELECTED ISSUES].

<sup>26</sup> U.S. GEN. ACCOUNTING OFFICE, REP. NO. GAO-02-47T, FUNDAMENTAL CHANGES NEEDED TO ENSURE SAFE FOOD 2 (2002), *available at* <http://www.gao.gov/new.items/d0247t.pdf>.

<sup>27</sup> For a succinct summary of FDA jurisdiction, see CRS PRIMER, *supra* note 2.

<sup>28</sup> *Id.*

<sup>29</sup> *Id.* For an insightful discussion of China's food industry, see GEOFFREY S. BECKER, CONG. RESEARCH SERV. FOOD AND AGRICULTURAL IMPORTS FROM CHINA (2008), <http://www.fas.org/sfp/crs/row/RL34080.pdf> [hereinafter CRS CHINESE IMPORTS].

<sup>30</sup> *See* COMM. TO ENSURE SAFE FOOD FROM PROD. TO CONSUMPTION, INST. OF MED. & NAT'L RESEARCH COUNCIL, ENSURING SAFE FOOD FROM PRODUCTION TO CONSUMPTION (1998).

<sup>31</sup> *See* SCI. BD., FOOD & DRUG ADMIN., FDA SCIENCE AND MISSION AT RISK: REPORT OF THE FDA SCIENCE BOARD'S SUBCOMMITTEE ON SCIENCE AND TECHNOLOGY (2008), *available at* [http://energycommerce.house.gov/Press\\_110/022508.ScienceBoardReport.EstimatedResources.pdf](http://energycommerce.house.gov/Press_110/022508.ScienceBoardReport.EstimatedResources.pdf).

<sup>32</sup> *See* CRS PRIMER, *supra* note 2; *see* GEOFFREY S. BECKER, CONG. RESEARCH SERV., FOOD SAFETY ON THE FARM: FEDERAL PROGRAMS AND SELECTED PROPOSALS (2009), *available at* <http://www.nationalaglawcenter.org/assets/crs/RL34612.pdf>; CRS SELECTED ISSUES, *supra* note 25; CRS CHINESE IMPORTS, *supra* note 29; GEOFFREY S. BECKER, CONG. RESEARCH SERV., SANITARY AND PHYTOSANITARY (SPS) CONCERNS IN AGRICULTURAL TRADE (2006), *available at*



Accountability Office (GAO),<sup>33</sup> former FDA officials who are now in academia,<sup>34</sup> public interest groups,<sup>35</sup> as well as a self-analysis written by FDA staff during President George W. Bush's administration.<sup>36</sup>

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<http://ncseonline.org/NLE/CRSreports/06Jul/RL33472.pdf>.

<sup>33</sup> The following list is not all-inclusive of GAO reports on food safety, but rather singles out those most relevant to the FDA's contribution to this mission: U.S. GOV'T ACCOUNTABILITY OFFICE, REP. NO. GAO-09-523, INFORMATION TECHNOLOGY: FDA NEEDS TO ESTABLISH KEY PLANS AND PROCESSES FOR GUIDING SYSTEMS MODERNIZATION EFFORTS (2009), *available at* <http://www.gao.gov/new.items/d09523.pdf> (explaining problems with the agency's computerized data analysis systems); U.S. GOV'T ACCOUNTABILITY OFFICE, REP. NO. GAO-08-435T, FEDERAL OVERSIGHT OF FOOD SAFETY: FDA'S FOOD PROTECTION PLAN PROPOSES POSITIVE FIRST STEPS, BUT CAPACITY TO CARRY THEM OUT IS CRITICAL (2008), *available at* <http://www.gao.gov/new.items/d08435t.pdf> [hereinafter GAO FDA CAPACITY] (explaining that the FDA must have more money, legal authority, and political will to implement the Bush Administration proposed plan for improving its food safety programs); U.S. GOV'T ACCOUNTABILITY OFFICE, REP. NO. GAO-08-909T, FEDERAL OVERSIGHT OF FOOD SAFETY: FDA HAS PROVIDED FEW DETAILS ON THE RESOURCES AND STRATEGIES NEEDED TO IMPLEMENT ITS FOOD PROTECTION PLAN (2008), *available at* <http://www.gao.gov/new.items/d08909t.pdf> (criticizing the FDA for failing to report in sufficient detail on its progress in implementing the Bush Plan); U.S. GOV'T ACCOUNTABILITY OFFICE, REP. NO. GAO-08-794, FOOD SAFETY: SELECTED COUNTRIES' SYSTEMS CAN OFFER INSIGHTS INTO ENSURING IMPORT SAFETY AND RESPONDING TO FOODBORNE ILLNESS (2008), *available at* <http://www.gao.gov/new.items/d08794.pdf> (highlighting efforts in Europe and Canada to implement more effective food safety systems); U.S. GOV'T ACCOUNTABILITY OFFICE, REP. NO. GAO-05-549T, OVERSEEING THE U.S. FOOD SUPPLY: STEPS SHOULD BE TAKEN TO REDUCE OVERLAPPING INSPECTIONS AND RELATED ACTIVITIES (2005), *available at* <http://www.gao.gov/new.items/d05549t.pdf> [hereinafter GAO SIMPLIFICATION] (urging the consolidation and simplification of the nation's food safety laws and the administrative structure employed to implement them); U.S. GOV'T ACCOUNTABILITY OFFICE, REP. NO. GAO-05-51, FOOD SAFETY: USDA AND FDA NEED TO BETTER ENSURE PROMPT AND COMPLETE RECALLS OF POTENTIALLY UNSAFE FOOD (2004), *available at* <http://www.gao.gov/new.items/d0551.pdf> [hereinafter GAO RECALLS] (concluding the recalls are always voluntary and poorly supervised, with the result that many are ineffective in removing contaminated food from homes); U.S. GEN. ACCOUNTING OFFICE, REP. NO. GAO-04-246, FOOD SAFETY: FDA'S IMPORTED SEAFOOD SAFETY PROGRAM SHOWS SOME PROGRESS, BUT FURTHER IMPROVEMENTS ARE NEEDED (2004), *available at* <http://www.gao.gov/new.items/d04246.pdf> (explaining the problems that undermine efforts to supervise the safety of imported fish); U.S. GEN. ACCOUNTING OFFICE, REP. NO. GAO/RCED-98-103, FOOD SAFETY: FEDERAL EFFORTS TO ENSURE THE SAFETY OF IMPORTED FOODS ARE INCONSISTENT AND UNRELIABLE (1998), *available at* <http://www.gao.gov/archive/1998/rc98103.pdf> [hereinafter GAO FOOD IMPORTS] (exploring the difficulties the FDA has had as a result of a small inspection force, increasing imports, and the difficulty of verifying that other countries effectively assure safety of their exports).

<sup>34</sup> See MICHAEL R. TAYLOR & STEPHANIE D. DAVID, STRONGER PARTNERSHIPS FOR SAFER FOOD: AN AGENDA FOR STRENGTHENING STATE AND LOCAL ROLES IN THE NATION'S FOOD SAFETY SYSTEM (2009), *available at* <http://www.rwjf.org/files/research/20090417foodsafetyfinalreport.pdf>; TOWARD SAFER FOOD:

In 2007, the GAO decided to include federal government oversight of food safety on its “high-risk series” list.<sup>37</sup> The high-risk list was initiated in 1990 as a tool for identifying government programs in need of urgent reform, either because they are subject to significant waste and fraud or because they need “broad-based transformation to address major economy, efficiency, or effectiveness challenges.”<sup>38</sup> To keep the implications of inclusion on the list appropriately dire, the GAO has targeted a limited number of programs in what it obviously considers to be in deep trouble; only thirty appeared on the list as of January 2009. The list includes areas of well-publicized and widespread concern, such as effective management of the Department of Homeland Security, which was listed in 2003, shortly after Congress created this huge, new entity. It also includes programs that only periodically come to the public’s attention, such as the National Flood Insurance Program, which was listed in 2006, as the implications of Hurricane Katrina for coastal property damage were becoming clear. The GAO’s impeccable reputation for objectivity and freedom from political interference should catapult “high-risk” programs to the top of the executive and legislative branches’ priorities for reform, spurring improvements that convince GAO to de-list the program. Unfortunately, reforms are not always forthcoming and several particularly intractable problems – for example, supply and weapons acquisition at the Department of Defense – have remained on the list since its inception in 1990.

The GAO was characteristically blunt in explaining its reason for listing food safety as a high priority risk:

[GAO added food safety in 2007] because 15 agencies collectively administer 30 food-related laws. Since then, the largest food-borne outbreak in the last 10 years was linked to *Salmonella* in fresh produce. Also, high levels of imported foods

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PERSPECTIVES ON RISK AND PRIORITY SETTING (Sandra A. Hoffmann & Michael R. Taylor eds., 2005).

<sup>35</sup> TRUST FOR AMERICA’S HEALTH, KEEPING AMERICA’S FOOD SAFE: A BLUEPRINT FOR FIXING THE FOOD SAFETY SYSTEM AT THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (2009), available at <http://healthyamericans.org/assets/files/2009FoodSafetyReport.pdf> (the FDA is housed at the department).

<sup>36</sup> INTERAGENCY WORKING GROUP ON IMPORT SAFETY, DEP’T OF HEALTH & HUMAN SERVS., ACTION PLAN FOR IMPORT SAFETY (2007), available at <http://www.importsafety.gov/report/actionplan.pdf>.

<sup>37</sup> U.S. GOV’T ACCOUNTABILITY OFFICE, REP. NO. GAO-09-271, HIGH-RISK SERIES: AN UPDATE 5 tbl.3 (2009), available at <http://www.gao.gov/new.items/d09271.pdf> [hereinafter GAO High Risk].

<sup>38</sup> *Id.* at 33.

underscore the urgency to revamp this system. About 15 percent of the overall U.S. food supply is imported, as is about 60 percent of fresh fruits and vegetables and over 80 percent of seafood.

...  
... Federal expenditures on food safety are not based on the volume of foods regulated by the agencies or consumed by the public. FDA is responsible for about 80 percent of the food supply and yet accounts for about 24 percent of expenditures.<sup>39</sup>

The FDA fields approximately 1,900 inspectors in regional offices throughout the United States, and has a staff of some 900 at its Washington D.C. headquarters.<sup>40</sup> As indicated by the PCA peanut saga, state and local agencies also inspect food production facilities, although the quality of the inspection and enforcement programs are often sub-par.<sup>41</sup> Information on the frequency of FDA inspections is somewhat inconsistent. The CRS reports that “various estimates of unannounced compliance inspections of domestic establishments by FDA officials range from once every five years to once every ten years, on average, although the agency *claims* to visit about 6,000 so-called high-risk facilities on an annual basis.”<sup>42</sup> The GAO’s analysis of FDA data showed that inspections of some 190,000 foreign food firms decreased from 211 in fiscal year 2001 to fewer than 100 in fiscal year 2007.<sup>43</sup>

In fiscal year (“FY”) 2009, the FDA’s budget for monitoring the safety of eighty percent of the nation’s food supply was \$649 million, plus another \$137 million for the regulation of animal drugs and feeds.<sup>44</sup> In dramatic contrast, the Department of Agriculture’s budget for monitoring the safety of twenty percent of the nation’s food supply was \$972 million.<sup>45</sup> President Obama’s budget for FY 2010 would add

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<sup>39</sup> *Id.* at 71.

<sup>40</sup> CRS PRIMER, *supra* note 2, at 2.

<sup>41</sup> See Gardiner Harris, *Ill from Food? Investigations Vary by State*, N.Y. TIMES, Apr. 20, 2009, at A1.

<sup>42</sup> GAO FDA CAPACITY, *supra* note 33 at 6.

<sup>43</sup> GAO FOOD IMPORTS, *supra* note 33, at 5.

<sup>44</sup> U.S. FOOD & DRUG ADMIN., DEP’T OF HEALTH & HUMAN SERVS., PROTECTING AMERICA’S FOOD SUPPLY: INVESTMENTS FOR SUPPLY CHAIN SAFETY AND SECURITY 9, <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM153494.pdf>.

<sup>45</sup> JIM MONKE, CONG. RESEARCH SERV., AGRICULTURE AND RELATED AGENCIES: FY 2010 APPROPRIATIONS 28 (2009), <http://www.nasda.org/File.aspx?id=24557>.

\$259 million to the FDA budget. If Congress approves the reforms to the FDA's legal authority contained in pending legislation, this influx of funding will strengthen the FDA's ability to promulgate new rules and significantly increase staffing at headquarters, which should grow to 854 Full-time Equivalents, or FTEs, while regional offices would field 2,165 inspectors.<sup>46</sup> These increases would allow the FDA to inspect high-priority domestic facilities more frequently, but they are unlikely to make much of a dent in the agency's limited ability to supervise foreign imports.

The FDA does not have existing authority to order recalls. Instead the FDA must rely on the cooperation of food manufacturers, processors, wholesalers, and retailers to accomplish the arduous and expensive job of extracting contaminated food from commerce. Indeed, the agency's legal impotence was noted by press covering the peanut scandal.<sup>47</sup> Consumer groups and independent experts have sharply criticized the FDA's lack of mandatory recall authority, and pending House and Senate reauthorization legislation would give the agency this authority.<sup>48</sup>

Some prominent members of the food industry and FDA career staff have argued that mandatory recall authority could interfere with the cooperative spirit that supposedly pervades industry and government collaboration during voluntary recalls, an ingredient they say is essential to the efficacy of the recall remedy, and would therefore make the FDA a less valuable partner in corporate efforts to encourage consumers to turn in tainted food.<sup>49</sup> Congress has thus far decided to ignore these arguments. Among other considerations, this rationale does not take into account the short-term economic pressures – and even sheer laziness or malfeasance – that can provoke food producers to cut corners, all of which were on full display in the PCA peanut incident. Kellogg, a major customer of PCA, clearly understood the implications for its business if peanut paste was contaminated by salmonella, and the company made an effort to forestall this kind of

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<sup>46</sup> For the granular detail of how the FDA would spend these amounts, see U.S. FOOD & DRUG ADMIN., FY 2010 EXHIBIT FOR CONGRESSIONAL APPROPRIATORS, available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM153496.pdf> (last visited Oct. 6, 2009).

<sup>47</sup> Gardiner Harris, *Peanut Product Recall Took Company Approval*, N.Y. TIMES, Feb. 3, 2009, at A13.

<sup>48</sup> Food Safety Enhancement Act, H.R. 2749, 111th Cong. § 111 (2009); FDA Food Safety Modernization Act, S. 510, 111th Cong. § 206 (2009).

<sup>49</sup> See VANESSA K. BURROWS, CONG. RESEARCH SERV., THE FDA'S AUTHORITY TO RECALL PRODUCTS 3 (2007), available at <http://www.nationalaglawcenter.org/assets/crs/RL34167.pdf>.

problem by deploying third-party inspectors to PCA's Georgia plant.<sup>50</sup> However, the inspector, who was paid by PCA and not Kellogg, was not only incompetent but overly friendly with the target of his efforts, sending a note by electronic mail announcing cheerfully, "You lucky guy. I am your AIB auditor. So we need to get your plant set up for any audit. . . . Thanks and Merry Christmas and Happy New Year to you and your family."<sup>51</sup> The inspector subsequently cleared the dates of the audit with plant personnel.<sup>52</sup>

In any event, the unfortunate reality is that even in the best of circumstances, recalls are notoriously difficult to implement and are not an effective substitute for preventive regulation. Because products are relatively inexpensive and purchases are so numerous, retailers rarely have easy access to the names and contact information of individual customers. Even if such information is available, recalls involving millions of units are daunting to implement. The GAO reported in 2004 that "most recalled food is not recovered," estimating that food recalls supervised by the FDA in 2003 recovered thirty-six percent of covered products.<sup>53</sup>

Of course, the fact that consumers do not take the trouble to return products does not mean that contaminated food is consumed. During the 2009 peanut scare, the FDA web site disseminating information regarding affected products was visited twenty-eight million times.<sup>54</sup> These figures indicate that national press attention motivates extensive public interest and suggest that, rather than returning contaminated food items, many consumers simply toss them in the trash. If these assumptions are correct, the real threats to public health lie in food consumed before researchers trace back the contamination and the multiple instances of small-scale contamination that do not receive intensive national coverage.

As a result of the growing threats to public health and steep costs to the food industry, the full spectrum of participants in the food safety debate agree that FDA regulators must emphasize programs that prevent outbreaks of contamination through the mandatory implementation of "food safety plans" that assess the risks posed by the processing that occurs at covered facilities. The House and Senate

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<sup>50</sup> See *supra* text accompanying note 13.

<sup>51</sup> E-mail from Pete Hatfield, Inspector, Am. Inst. of Banking, Inc., to Sammy Lightsey, Plant Manager, Peanut Corp. of Am. (Dec. 22, 2008, 10:55:08), available at [http://energycommerce.house.gov/Press\\_111/20090319/Email%20exchange%20Hatfield%20Lightsey%20December%2031%202008.pdf](http://energycommerce.house.gov/Press_111/20090319/Email%20exchange%20Hatfield%20Lightsey%20December%2031%202008.pdf).

<sup>52</sup> *Id.*

<sup>53</sup> GAO RECALLS, *supra* note 33.

<sup>54</sup> See Sundlof Testimony, *supra* note 4, at 9.

bills both have provisions requiring owners, operators, or agents of covered facilities to prepare such plans under guidance issued by the FDA and to update the plans periodically.<sup>55</sup> To ensure that the FDA has a credible presence in policing compliance with these plans, the bills take the unusual step of mandating how often covered facilities must be inspected. The House-passed legislation is more specific requiring that the FDA rank facilities as “Category 1/high-risk,” “Category 2/low-risk,” or as a “Category 3/facility that holds food.”<sup>56</sup> The House directs the FDA to randomly inspect Category 1 facilities at least every six to twelve months, Category 2 facilities at least every eighteen months to three years, and Category 3 facilities at least every five years. In contrast, the Senate would require inspection of “high-risk” facilities every two years during the first two years after the date of enactment, and every year following that initial period, while “non-high-risk” facilities must be inspected at least once every four years.<sup>57</sup>

These mandatory timetables are an important reform for an agency that exhibits such acute dysfunction. But if Congress does not deliver the funding necessary to meet these aggressive schedules, the provisions will degenerate into symbolic law. The bills do not contain so-called “citizen suit” provisions that would allow concerned parties to take the agency to court if it does not meet the new statutory deadlines. These citizen suit provisions are common in the federal environmental laws,<sup>58</sup> and court orders have played an important role in pressuring the Environmental Protection Agency to ask Congress for the funds needed to implement statutory mandates.

As for imports, neither bill would adopt the most aggressive reform proposed by the GAO and other independent observers.<sup>59</sup> Before meat and poultry are imported to this country, the U.S. Department of Agriculture must conduct an evaluation determining that the source country has a regulatory system in place that is basically equivalent to the system we have in the United States.<sup>60</sup> This so-

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<sup>55</sup> Food Safety Enhancement Act, H.R. 2749, 111th Cong. § 101 (registration); H.R. 2749 § 102 (hazard analysis and risk-based preventive controls) (2009); FDA Food Safety Modernization Act, S. 510, 111th Cong. § 102 (2009) (relating to registration of food facilities); § 103 (hazard analysis and risk-based preventive controls).

<sup>56</sup> H.R. 2749, § 105 (2009).

<sup>57</sup> S. 510 § 201 (relating to the targeting of inspection resources for domestic facilities, foreign facilities, and ports of entry).

<sup>58</sup> See, e.g., 33 U.S.C. § 1365 (2006) (authorizing citizen suits for violations of the Clean Water Act).

<sup>59</sup> See, e.g., GAO FOOD IMPORTS, *supra* note 33, at 21-26.

<sup>60</sup> See generally OFFICE OF INT’L AFFAIRS, U.S. DEP’T OF AGRICULTURE, FOOD SAFETY INSPECTION SERVICE, U.S. DEP’T OF AGRICULTURE, PROCESS FOR

called “equivalency authority” allows American regulators to “transfer the primary food safety responsibility to the exporting country,” in effect leveraging their own resources by evaluating programs periodically rather than posting hundreds, even thousands, of inspectors at U.S. ports.<sup>61</sup> As Senate leaders began their consideration of food safety legislation in January 2009, they apparently concluded that they could not muster enough political support to overcome strenuous food industry resistance to such a system and that the money needed to implement it would not be forthcoming. The legislation adopts compromises on imports that are likely to prove far less effective. The House-passed bill authorizes the FDA to require “certification” of food imports if the FDA decides, in its discretion, that the process would assist the agency in deciding whether to admit a potentially risky category of food.<sup>62</sup> Certifications could be performed by “qualified certifying entities,” an opaque term that can include regulators from other countries’ governments or accredited third-party inspectors recognized by the FDA.<sup>63</sup> Given the remarkably incompetent performance of national third party inspectors during the PCA peanut scandal and shortcomings of regulatory programs in China and other Asian countries that have become the leading sources of such high-hazard commodities as fish, neither alternative is likely to provide satisfactory protection for quite some time.

The leading Senate legislation is even weaker. It places the burden on importers to “perform risk-based foreign supplier verification activities in accordance with regulations promulgated [by the FDA].”<sup>64</sup> An importer who violates these requirements commits a “prohibited act” under the Senate bill but is liable only for the misdemeanor penalty available under existing law.<sup>65</sup>

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EVALUATING THE EQUIVALENCE OF FOREIGN MEAT AND POULTRY FOOD REGULATORY SYSTEMS (2003), *available at* <http://www.fsis.usda.gov/OPPDE/IPS/EQ/EQProcess.pdf> (detailing the legal authority requiring and process for performing equivalency evaluations).

<sup>61</sup> GAO FOOD IMPORTS, *supra* note 33, at 24.

<sup>62</sup> H.R. 2749 § 109 (2009).

<sup>63</sup> *Id.*

<sup>64</sup> FDA Food Safety Modernization Act, S. 510, 111th Cong. § 301 (2009) (relating to foreign supplier verification program).

<sup>65</sup> *Id.*; Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331 (2006).

## II. CRIMINAL ENFORCEMENT AS ANTIDOTE TO DYSFUNCTION

### A. The “E(nforcement) Word”

The FDA’s regulatory dysfunction is the product of two powerful and converging trends. The first trend is a highly successful campaign to discredit federal regulatory intervention in the so-called “free” market.<sup>66</sup> This campaign, mounted by the nation’s most powerful business interests, began with the election of President Ronald Reagan and peaked during the administration of George W. Bush (“Bush II”). During the entire Bush II period, health and safety laws were left to molder without updating amendments;<sup>67</sup> the White House stifled regulatory proposals that had been in the pipeline for years, including those prompted by non-discretionary statutory mandates;<sup>68</sup> and budgets were slashed with the full cooperation of agency political appointees.<sup>69</sup>

The dynamics that advanced the campaign to deregulate changed with the 2008 presidential election. At present, proponents are waging a ferocious battle to maintain their influence in the wake of the Enron, WorldCom, and Madoff scandals, acute public distress over the global economic recession that began in 2008, conspicuous holes in the regulatory safety net that are manifested as salmonella-laced

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<sup>66</sup> This word is placed in quotation marks because the economic dynamics of the American and global marketplaces are heavily influenced by government subsidies, tax loopholes, and financial regulation, making the free market described by economists and advocates of deregulation a theoretical construct that has little relationship with reality.

<sup>67</sup> The food safety provisions of the Food, Drug, and Cosmetic Act were last amended in 1997. See Food & Drug Administration Modernization Act (FDAMA) of 1997, Pub. L. No. 105-115, §§ 301-309, 111 Stat. 2296, 2350-56. Other laws in desperate need of change include the Occupational Safety and Health Act of 1970, 29 U.S.C. §§ 651-678 (2006), last amended in 1998, by the Occupational Safety and Health Administration Compliance Assistance Authorization Act of 1998, Pub. L. No. 105-197, 112 Stat. 638, and the Clean Water Act, last amended in 1987, by the Federal Water Pollution Control Act Amendments of 1987, Pub. L. No. 100-4, §§ 301-306, 101 Stat. 29-37.

<sup>68</sup> For example, the Bush II Administration decided to postpone strong regulation of mercury emissions from power plants until 2018. Beth Daley, *EPA Rule Will Limit Power-Plant Mercury*, BOSTON GLOBE, Mar. 15, 2005, at A1.

<sup>69</sup> See, e.g., Stephen Labaton, *Safety Chief Is Opposing More Money*, N.Y. TIMES, Oct. 30, 2007, at C1 (describing a request by Nancy Nord, chair of the Consumer Product Safety Commission, that Congress abandon plans to increase her agency’s budget).



peanut butter and lead-coated imported toys,<sup>70</sup> and the election of President Obama, who defines government's role as doing for people what "we cannot do for ourselves."<sup>71</sup> The president has lent his strong support to food safety reform, in particular with respect to the FDA.<sup>72</sup> These events and the president's attitudes have clearly slowed the advance of deregulation, although the movement remains quite active in areas like the debate over climate change legislation.

The second converging trend is a Congress' systematic underfunding of regulatory agencies by Congress. These budget gaps make the agencies far more susceptible to assertions that they must tread softly in controlling business practices because they lack the resources they need to defend their rules against strong attack, both during the rulemaking process and in court. As serious, shortfalls deprive the agencies of the resources they need to make their enforcement programs appear even minimally credible, as illustrated by the statistics regarding the FDA's ability to inspect food processing facilities cited earlier.<sup>73</sup> Eventually, this noxious combination of demoralized and underfunded bureaucracy hurts businesses as well as consumers; consider the \$1 billion in losses the peanut industry suffered as a result of the caused by the PCA peanut scandal just among other producers of peanut products.<sup>74</sup>

Despite the obvious damage legitimate businesses suffer as a result of regulatory dysfunction, corporate executives rarely embrace affirmative reforms. Food safety is a modest, partial exception to this general rule, at least up to a point. Sensing a turning tide of political support, major trade associations have testified before Congress in support of legislation that would expand FDA food safety programs. But the most prominent have drawn the line at strengthened penalties and enforcement. Consider the following statement from Cal Dooley, former president and chief executive officer of the Grocery Manufacturers Association (GMA), which is among the most prominent industry groups participating in the debate:

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<sup>70</sup> See, e.g., Louise Story, *Lead Paint Prompts Mattel to Recall 967,000 Toys*, N.Y. TIMES, Aug. 2, 2007, at C1 (describing recalls of toys coated with lead paint and imported from China).

<sup>71</sup> Barack Obama, U.S. Senator, Closing Argument Speech at the Canton Memorial Civic Center (Oct. 27, 2008), available at [http://blogs.suntimes.com/sweet/2008/10/obama\\_closing\\_argument\\_speech\\_1.html](http://blogs.suntimes.com/sweet/2008/10/obama_closing_argument_speech_1.html).

<sup>72</sup> Gardiner Harris, *President Plans Team to Overhaul Food Safety*, N.Y. TIMES, Mar. 15, 2009, at A24.

<sup>73</sup> See CRS PRIMER, *supra* note 2, at 2; GAO FOOD IMPORTS, *supra* note 34.

<sup>74</sup> Fredrix, *supra* note 16 (describing a cost estimate by Don Koehler, of the Georgia Peanut Commission, of the costs imposed on rural peanut producers by the PCA scandal).

We also strongly oppose costly new regulatory requirements, including provisions that provide FDA inspectors with broad authority to review the adequacy of food safety plans . . . . While we support the requirement that all food companies have a food safety plan, we believe food companies should be given the discretion to identify appropriate safety controls . . . . Prescriptive, across-the-board, new regulatory requirements will stifle innovation, divert resources from proven food safety measures, and will increase food costs at a time of record food inflation.

While we believe that some facilities deserve greater scrutiny than others, we opposed rigid inspection schedules and instead believe that FDA inspections should be based upon risk. We also strongly opposed needless civil penalties and reinspection fees. *Food companies have powerful incentives to ensure the safety of food products and ingredients and current law already provides a wide range of enforcement tools, including seizure, injunction, and civil and criminal penalties.* Giving FDA the power to assign massive fines and fees will dramatically alter the cooperative relationship between FDA and the food industry and will create a powerful incentive for FDA to find violations regardless of merit.<sup>75</sup>

Dooley's demand for a "cooperative" relationship with government coincides with what has happened to enforcement over the course of the deregulatory campaign, when conservatives argued that the country would be better served if government committed resources to "compliance assistance," a term of art for government programs that seek to educate regulated industries about the elaborate regulatory requirements that apply to their operations.<sup>76</sup> Under Presidents William Clinton and George H.W. and George W. Bush, such programs flourished, although efforts to assess their effectiveness are virtually impossible because no one kept reliable statistics regarding either the number of businesses involved in compliance counseling or the impact of such educational efforts on the incidence of noncom-

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<sup>75</sup> *FDA Overhaul: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 110th Cong. (Apr. 24, 2008) (statement of Cal Dooly, President & CEO, Grocery Mfg. Ass'n) (emphasis added).

<sup>76</sup> See, e.g., Mark Wilson, *Save Lives by Cutting Red Tape: Redefine the Federal Role in Workplace Safety and Health* (Sept. 5, 1995), available at [http://www.heritage.org/research/socialsecurity/upload/89740\\_1.pdf](http://www.heritage.org/research/socialsecurity/upload/89740_1.pdf) (arguing that the OSHA should work cooperatively with businesses, for example, by making compliance assistance a central component of its programs).

pliance among those companies.<sup>77</sup> The arguments made by Bush II appointees and food industry representatives to the effect that the FDA should not receive mandatory recall authority and instead should continue to rely on voluntary cooperation by companies that produced tainted food are direct descendants of this compliance counseling approach.<sup>78</sup>

The question remains whether Senator Durbin's (D-Ill.) decision to omit any changes to the FDA's authority to impose criminal penalties for food safety violations is also based on these considerations. Senator Durbin introduced S. 510 on March 3, 2009, with ten co-sponsors — five Democrats and five Republicans. The Democrats included Senators Christopher Dodd (D-Conn.), Roland Burris (D-Ill.), Amy Klobuchar (D-Minn.), Edward Kennedy (D-Mass., since deceased), and Tom Udall (D-Utah). The Republicans included Senators Lamar Alexander (R-Tenn.), Richard Burr (R-N.C.), Saxby Chambliss (R-S.C.), Judd Gregg (R-N.H.), and Johnny Isakson (R-Ga.). With the possible exception of Senator Gregg, the Republicans in this group are pointedly conservative and generally support business interests, justifying the speculation that Senator Durbin shaped the content of his bill in order to achieve a bipartisan approach that would speed the legislation's passage. Omitting stronger criminal penalty provisions would serve as a logical trade-off in any logrolling along these lines that may have occurred behind the scenes. The inclusion of amendments strengthening criminal liability in parallel House legislation, and the prominence of a series of food safety scandals during the period when Senator Durbin was drafting S. 510, make it highly unlikely that the decision to omit these reforms was anything but a conscious political choice.

#### B. Responsible Corporate Officers

Following the hypothesis that leaving enhanced criminal penalties out of the legislation was accomplished by industry lobbying, what motivates those attitudes? After all, the observation that the misdemeanor punishment is an ineffective deterrent would logically suggest that business executives have little to fear from enforcement of these provisions. Not only are any eventual penalties light, but federal prosecutors are highly unlikely to spend scarce resources on cases that do not bring felony convictions.

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<sup>77</sup> See, e.g., CLAUDIA COPELAND, CONG. RESEARCH SERV., REINVENTING THE ENVIRONMENTAL PROTECTION AGENCY AND EPA'S WATER PROGRAMS (1996), available at <http://ncseonline.org/Nle/Crsreports/water/h2o-20.cfm>.

<sup>78</sup> See BURROWS, *supra* note 49 and accompanying text.

Industry's antipathy to the FDA's criminal authority undoubtedly is motivated by two prosecutions of purveyors of tainted food that led to landmark Supreme Court decisions changing the fundamental premises of criminal punishment for so-called public welfare offenses.<sup>79</sup> The "responsible corporate officer" doctrine that resulted from these cases holds that executives at the top of a corporate hierarchy, who were not directly involved in committing violations but were in a position to implement policies that would have prevented the offensive conduct, can be held criminally liable to the same extent as their most culpable underlings.

In a classic 1933 article in the *Columbia Law Review*, Professor Francis Bowes Sayre described such cases as the product of an "increasingly complex social order [that] required additional regulation of an administrative character unrelated to questions of personal guilt."<sup>80</sup> Professor Sayre was scandalized by this development and warned that such prosecutions should be carefully limited to "public welfare offenses involving light penalties."<sup>81</sup> Whether a federal prosecution commanding a sentence of up to one year in jail would be sufficiently light from his perspective is unclear but, in any event, the Supreme Court did not share his compunction.

The first case involved the prosecution of the Buffalo Pharmacal Company, Inc., along with its president and general manager Joseph H. Dotterweich, under the misdemeanor provisions of the Food and Drug Act for shipping "misbranded drugs" – to wit, "cascara compound" (or "Hinkle Pills") containing strychnine sulfate.<sup>82</sup> The National Formulary listing of acceptable ingredients for this medication had excluded that chemical in 1939.<sup>83</sup> The specific issue before the court was whether Dotterweich could be held liable as a "person" under the Act. Justice Frankfurter's opinion on behalf of five to four majority declared that the prosecution was based on a:

now familiar type of legislation whereby penalties serve as effective means of regulation. Such legislation dispenses with

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<sup>79</sup> See *id.*

<sup>80</sup> Francis Bowes Sayre, *Public Welfare Offenses*, 33 COLUM. L. REV. 55, 67 (1933).

<sup>81</sup> *Id.* at 83.

<sup>82</sup> *United States v. Buffalo Pharmacal Co., Inc.*, 131 F.2d 500, 501-02 (2d Cir. 1942).

<sup>83</sup> The National Formulary is an official publication, issued first by the American Pharmaceutical Association and now yearly by the United States Pharmacopeial Convention, that gives the composition, description, method of preparation, and dosage for drugs. MedicineNet.com, Definition of National Formulary, Dec. 7, 2003, <http://www.medterms.com/script/main/art.asp?articlekey=25605>.

the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but *standing in responsible relation to a public danger*.<sup>84</sup>

The 1975 case took this departure from traditional *mens rea* requirements to its logical conclusion. *United States v. Park* involved the poor maintenance of a large Baltimore warehouse used to store boxed food products by Acme Markets, Inc., a national retail food chain with 36,000 employees, 874 retail outlets, and 16 warehouses. The warehouse was plagued by rodents, some of which had managed to chew through the food packaging in addition to leaving feces and urine around the facility, and the company had undergone an initial inspection by FDA officials that lasted for twelve days and produced a letter to company president John R. Park demanding corrective action. He delegated responsibility for this work to his Baltimore division vice president. When FDA representatives returned to re-inspect the facility four months later, conditions were improved, but rodent infestation persisted and the government decided to prosecute Park criminally.

Unlike Dotterweich's modest repackaging operation, which bought drugs wholesale and shipped them to retailers with its own label, Acme's operations were large and sprawling. Park defended himself on the basis that he was not directly responsible for sanitary conditions at the company's storage facilities and that he had delegated these tasks to responsible subordinates. The Court of Appeals for the Fourth Circuit reversed his conviction by a jury<sup>85</sup> and the government appealed to the Supreme Court. Alarmed by the implications of the Court's decision to grant *certiorari*, a broad coalition of industry groups filed amici briefs.

The central issue in the case was whether the trial court judge had erred in failing to instruct the jury that the prosecution must shoulder the burden of proving Park guilty of "wrongful action," a term that implies affirmative behavior.<sup>86</sup> Writing on behalf of a six to three majority, Justice Burger cited substantial precedent concluding that "knowledge or intent were not required to be proved" and that "an omission or failure to act" is a sufficient basis for imposing "a respon-

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<sup>84</sup> *United States v. Dotterweich*, 320 U.S. 277, 280-81 (1943) (emphasis added).

<sup>85</sup> *United States v. Park*, 499 F.2d 839 (4th Cir. 1974), *rev'd*, 421 U.S. 658 (1975).

<sup>86</sup> *See United States v. Park*, 421 U.S. 658, 675 (1975).

sible corporate agent's liability."<sup>87</sup> "It was enough in such cases that, by virtue of the relationship [Park] bore to the corporation, [Park as an] agent had the power to prevent the act complained of."<sup>88</sup>

Regardless of the harshness of the penalties at stake in any given prosecution, the power of the *Park* and *Dotterweich* holdings cannot help but leave every well-informed executive experiencing a combination of resentment and anxiety. In large corporations, the distance between plant or warehouse supervisors is great, from bureaucratic and geographical perspectives. Any lawyer who has counseled clients who belong to the managerial pool in such organizations and are responsible for compliance with complex health and safety regulations – and the author spent seven years engaged in that activity – knows that the mere initiation of a criminal investigation is considered disastrous, no matter what its outcome. Unlike borderline financial practices – and perceptions in that arena are also evolving rapidly – managers cannot defend themselves by arguing that competitors were engaged in the same activities. Rather, they find themselves accused of a crime that threatens people's health, spreading an ethical stain that is difficult to escape once the mere fact of the accusation becomes known, even if the knowledge is confined within the corporation.

Two questions remain, however: (1) is anxiety about potentially unfair prosecution based in reality and, as important; (2) should these objections be ignored by policy-makers intent on revamping the food safety system in the United States?

### C. Monster in the Closet?

Viewed from the perspective of the FDA's actual track record on enforcement, anxiety about prosecution as a responsible corporate officer is analogous to children's fear of the monster in the closet. No doubt the terror is real, and no doubt the closet is empty.

Under the *2008 Federal Sentencing Guidelines Manual*, violations of section 331 of the Food, Drug, and Cosmetic Act are characterized as a "Base Offense Level 6," meaning that a conviction would trigger a sentence of between zero and six months in jail before the "criminal history points" of the individual defendant are considered.<sup>89</sup> Even after those points are added, however, sentencing guidance does not change; the person with the worst history would still be exposed under the guidance to a zero to six month sentence. According to the

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<sup>87</sup> *Id.* at 670-71.

<sup>88</sup> *Id.* at 671.

<sup>89</sup> U.S. SENTENCING COMM'N, FEDERAL SENTENCING GUIDELINES MANUAL § 2N2.1(a) (2008), available at [http://www.ussc.gov/2008guid/CHAP2\\_L-X.pdf](http://www.ussc.gov/2008guid/CHAP2_L-X.pdf).

*Federal Justice Statistics* kept by the U.S. Department of Justice, eighty-nine percent of defendants were charged with felony offenses in FY 2006 (the last year for which such information is available).<sup>90</sup> In order of priority, thirty-eight percent were charged with a “public-order offense,” including twenty percent for immigration violations and eleven percent for weapons violations, and thirty-seven percent were charged with a drug offense.<sup>91</sup>

Of course, the Department of Justice cannot prosecute if it does not get case referrals from the FDA. The agency’s statistics reveal an extraordinarily weak track record for criminal investigations and case referrals across-the-board. The FDA’s Office of Criminal Investigations reported 196 convictions in prosecutions for all violations of its statutes in FY 2004; 270 in FY 2005; 279 in FY 2006; 344 in FY 2007; and 369 in FY 2008.<sup>92</sup> The FDA Center for Food Safety and Applied Nutrition (CFSAN) executed two seizures in FY 2008 (the agency does not report how many products or product units were involved) and issued three injunctions.<sup>93</sup>

As for the objections that future application of the responsible corporate officer doctrine to food safety cases would do little more than persecute the well-meaning, potentially driving the worst culprits underground and discouraging small and mid-size businesses from coming forward for compliance assistance, two responses are possible. The enforcement track record in other contexts where the doctrine was applied does not substantiate such claims. Second, the FDA has few alternatives to deterrence-based enforcement in the absence of massive budget increases that seem very unlikely.

The responsible corporate officer doctrine is admittedly stringent and, if applied to insignificant or inadvertent violations, might well strike judges and juries as unfair. However, critics of the doctrine are hard-pressed to find prominent examples of such abuses in the arena of environmental law, where it has been vigorously enforced. For example, during the early years of the Clinton Administration, Professor Richard Lazarus raised the specter of prosecutions for environ-

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<sup>90</sup> Bureau of Justice Statistics, U.S. Dep’t of Justice, *Federal Justice Statistics, Adjudication*, May 28, 2009, <http://www.ojp.usdoj.gov/bjs/fed.htm#Adjudication>.

<sup>91</sup> *Id.*

<sup>92</sup> Food & Drug Admin., *Enforcement Story: Fiscal Year 2008*, at 10-18 (2009), available at <http://www.fda.gov/ICECI/EnforcementActions/EnforcementStory/default.htm>.

<sup>93</sup> *Id.* at 4-31. The agency sells the printed version of the document that contains these statistics for a whopping \$327. See Food & Drug Admin., *Product Details, FDA Enforcement Story*, <http://www.fdanews.com/store/product/detail?productId=26366> (last visited Oct. 5, 2009).

mental crimes that would punish corporate officers who had tried in good faith to comply with complex, even obscure, regulations. He argued for changes that would circumscribe the government's discretion under what he saw as unduly vague statutory language.<sup>94</sup> Lois Schiffer, Assistant Attorney General for the Environment and Natural Resources Division, and her colleague James Simon, rebutted these concerns, arguing that the Justice Department operated within a series of institutional constraints unrecognized by Lazarus and did, in fact, exercise its discretion wisely, confining prosecution to cases where conduct was egregious.<sup>95</sup>

As for the arguments that strong criminal enforcement will drive culprits underground while cutting off others from compliance counseling, the most compelling response may well be a pragmatic one. The utility for agencies like the FDA of robust criminal enforcement programs grows and intensifies in inverse proportion to their resources. When funding is plentiful and the number of industry players is relatively small, agencies can afford to do the individualized inspections that provide the kind of supportive compliance counseling envisioned by the GMA's Dooley. Agencies need substantial funding to field enough inspectors to visit plants frequently, making recommendations to improve compliance, and following up to determine that those suggestions are implemented. Unless compliance counseling is carried out in this intensive manner, it is highly unlikely to work, especially with respect to companies like the peanut producer PCA that provide ingredients for finished products and therefore do not risk priceless reputational damage at the retail level. Superficial counseling efforts, such as sponsoring training conferences for small and mid-size company employees, are unlikely to promote the profound changes in corporate culture required to jump-start a full-fledged compliance program.

The days of a simple industry structure and ample inspection staff are over for the FDA, if they ever existed. The sheer size and complexity of the food industry, which extends not only from farm to table but from one side of the world to the other, defeat any realistic hope of reverting to that kind of cooperative approach. The GMA is right that the government needs producers to cooperate with its effort to prevent food-borne illness. It is just as certainly wrong that coop-

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<sup>94</sup> Richard J. Lazarus, *Meeting the Demands of Integration in the Evolution of Environmental Law: Reforming Environmental Criminal Law*, 83 GEO. L.J. 2407 (1995).

<sup>95</sup> Lois J. Schiffer & James F. Simon, *The Reality of Prosecuting Environmental Criminals: A Response to Professor Lazarus*, 83 GEO. L.J. 2531, 2532 (1995).



eration by even the largest, well-meaning companies can fill the yawning gaps left by the absence of deterrence-based enforcement.

The concern that an aggressive criminal prosecution program will drive the worst actors underground would be more credible in an industry comprised primarily of small and mid-sized, independent producers who marketed directly to consumers. In contrast, as the PCA saga demonstrates, large companies like Kellogg and Nestlé are deeply concerned about the purity of the peanut ingredients they purchased from PCA. The first multinational, Kellogg may well have made serious errors in setting up its program for requiring third-party audits allowing PCA to hire and therefore control the firm providing the inspectors, the American Institute of Baking.<sup>96</sup> Kellogg continued to do business with PCA at its peril. In contrast, Nestlé's inspectors discovered the grievous conditions at the PCA plant and cut the company out of its supply chain.<sup>97</sup> These episodes show that well-run, third-party audits, supervised by large producers, could work to protect the public if their quality was strong enough to result in the economic isolation of companies like PCA.

### III. PROSPECTS FOR REFORM

The gist of the debate between Professor Lazarus and former Assistant Attorney General Schiffer, regarding the fairness of criminal prosecution under the federal environmental laws, boiled down to a fundamental clash over the reliability of prosecutorial discretion as the palliative that makes charging individual responsible corporate executives fair or unfair. In that context, the courts have held that under the responsible corporate officer doctrine, prosecutors need not prove that a defendant actually knew that certain conduct violated a specific law. Rather, the prosecution's burden was to prove that defendant, no matter how high up in the corporate hierarchy, was aware of the offensive conduct – for example, burying discarded chemicals in an unlined pit in the ground.<sup>98</sup> Lazarus argued that because the laws and their implementing regulations are extraordinarily complex, the responsible corporate officer doctrine permits prosecution of individual conduct that might not reflect sufficient culpability because noncompliance could so easily arise from honest mistake or confusion. Therefore, Congress should consider amending the law to circumscribe the doctrine. Schiffer responded that several external norms, especially the need to prove one's case to federal judges and juries, gave prosecutors

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<sup>96</sup> See *supra* text accompanying notes 12, 50-51.

<sup>97</sup> See *id.*

<sup>98</sup> See *United States v. Dee*, 921 F.2d 741 (4th Cir. 1990).

adequate incentives to avoid overreaching and that Lazarus's proposals were both unnecessary and unwise. Reviving these arguments during a period when the FDA is not developing cases against many people, even for egregious conduct, may seem peculiarly academic, an unflattering characterization that the author takes quite seriously. But on the chance that more explicit language restricting abuse of the doctrine could overcome the objections of a sufficient number of senators to obtain the conversion of a misdemeanor into a felony penalty, this article takes a stab at walking the middle line between the Lazarus/Schiffer debate.

In 1990, the British Parliament enacted the Food Safety Act, which imposes criminal penalties for "offences" of up to two years in jail, a £20,000 fine, and cancellation of a firm's license or registration.<sup>99</sup> "Offence" is defined, *inter alia*, as "render[ing] any food injurious to health by means of . . . adding any article or substance to the food."<sup>100</sup> The definition also includes the sale of food that is "injurious to health" or "unfit for human consumption."<sup>101</sup> The Act also applies a version of the responsible corporate officer doctrine: a "director, manager, secretary or other similar officer," or "any person . . . purporting to act in any such capacity," is liable to the same extent as the corporation if the violation is committed with the "consent or connivance" of the individual.<sup>102</sup>

To modulate the application of strict liability and give food processors an incentive to self-regulate, the British law creates a "due diligence" defense allowing the accused to prove that she "took all reasonable precautions and exercised all due diligence to avoid the commission of the offence."<sup>103</sup> Consistent with responsible corporate officer enforcement, these efforts must cover any person under the control of the defendant.<sup>104</sup> The law suggests that to prove diligence, a person could show that commission of the offense was due to an "act or default" either of a person "not under his control" or done in "reliance on information supplied by such a person."<sup>105</sup> This provision could be read to exempt manufacturers such as Kellogg from acts or omissions of its suppliers, such as PCA. However, this language is joined by the word "and" with two additional provisos.

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<sup>99</sup> Food Safety Act, 1990, c. 16, § 35 (Eng.).

<sup>100</sup> § 7.

<sup>101</sup> § 8(2).

<sup>102</sup> § 36.

<sup>103</sup> § 21(1).

<sup>104</sup> § 21(3).

<sup>105</sup> § 21(3)(a).

- The accused carried out all “checks of the food in question as were reasonable” or that “it was reasonable” for the accused “to rely on checks carried out by the person who supplied the food to him;” and
- The accused “did not know and had no reason to suspect” that the “act or omission would amount to an offence.”<sup>106</sup>

A detailed examination of how the due diligence defense could or should be implemented is beyond the scope of this article. Four reference points that flesh out the proposal to adopt it in the United States should assist readers to make a threshold assessment of its desirability.

First and foremost, the defense should not be applicable to the conduct exemplified by the PCA peanut scandal because that company’s executives failed to make reasonable efforts to ensure the safety of the food they processed. Ironically, one of the strongest arguments in potential defendants’ favor, should the PCA criminal case ever go to trial, is that Georgia state inspectors did not cite the company for its own mistakes. Yet those mistakes were anything but subtle or hidden. This anomaly suggests that the due diligence defense should be conditioned on federal “overfilling” authority: that is, favorable state inspections should not foreclose initiation of a federal prosecution. This approach would forestall collusion between underfunded and incompetent state inspectors and bad corporate actors.

Both the House and Senate FDA reform bills strengthen the requirement in existing law that food processing facilities register, by adding requirements that they register annually or biennially, and that they update their registration within thirty days after any change in critical information, such as ownership or scope of operation.<sup>107</sup> Foreign facilities providing food for American consumers are also required to register.<sup>108</sup> Failing to register should constitute a rebuttable presumption that the facility’s owner, operator, or agent cannot meet the burden of proof under the due diligence defense, with only cases involving legitimate disputes at the borderline of the new law’s definition of what constitutes a covered facility creating justification for

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<sup>106</sup> § 21(3)(b)-(c).

<sup>107</sup> *Compare* Food Safety Enhancement Act, H.R. 2749, 111th Cong. § 101(b) (2009) (annual registration), *and* FDA Food Safety Modernization Act, S. 510, 111th Cong. § 102 (2009) (requiring biennial registration), *with* 21 U.S.C. § 350d (2006) (requiring initial registration only).

<sup>108</sup> H.R. 2749, §§ 204-205 (2009) (registration for commercial importers of food and customs brokers); S. 510 §§ 301-309 (2009) (foreign supplier verification program).

overturning the presumption. This scheme could be set forth in legislative history.

Third, the bills also require the preparation and implementation of “hazard analysis and risk-based preventive controls” plans and “food safety plans” by owners, operators, or agents of covered facilities.<sup>109</sup> Enforcing criminal penalties against companies that prepare plans that are inadequate or that prepare adequate plans but do not implement them effectively, will involve more complex deliberations among prosecutors, regulators, and defense attorneys. Congress should require the Department of Justice, in consultation with the FDA, to prepare detailed guidelines on how it will exercise its prosecutorial discretion. In general, a company that makes a good faith effort to comply with planning requirements, and that establishes a robust system for conducting internal self audits of its plan’s procedures, should be exempt from criminal prosecution.

Fourth, and arguably most important, the Department of Justice should make it a priority to prosecute violations of safety requirements by importers of food products. The abandonment of any effort to mandate that the FDA employ a FSIS approach to certifying the efficacy of exporting nations’ regulatory systems should come with the recognition that the only way to protect public health in this country is to place a far heavier burden on importers to ensure that they verify minimal safety practices at the food facilities where their products originate.

## CONCLUSION

In an era when Congress must move quickly and with determination to reclaim the efficacy of the FDA’s regulatory programs for food safety, but is unwilling to increase the agency’s funding to the point that traditional inspection programs can coax food producers into compliance, deterrence-based enforcement is the best alternative for reform. Criminal penalties must be an integral component of that approach. Industry fears of the unfair exercise of prosecutorial discretion are outweighed by the urgent need resuscitate a safer marketplace. Adopting a due diligence defense modeled on England’s food safety law is a promising way to balance these concerns and imperatives.

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<sup>109</sup> H.R. 2749, § 102; S. 510 § 103 (relating to Hazard Analysis and Risk-Based Preventive Controls). Both bills leave existing Hazard Analysis Critical Control Point (HACCP) plan regulations in place.

